

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA)	NO. 4:17-CR-00403
)	
v.)	
)	(JUDGE BRANN)
)	
RAYMOND KRAYNAK,)	
Defendant)	(ELECTRONICALLY FILED)

GOVERNMENT'S BRIEF IN OPPOSITION TO DEFENDANT'S
MOTION *IN LIMINE* TO PRECLUDE EVIDENCE
UNDER F.R.E. 402, 403 AND 404

The United States hereby opposes defendant Raymond Kraynak's motion *in limine* to preclude evidence under Federal Rule of Evidence 402, 403, and 404. Doc. 119; 120. In support of its opposition the United States submits the following grounds.

I. FACTUAL BACKGROUND

A. Overview

Raymond Kraynak was a Doctor of Osteopathy (D.O.) who practiced medicine at the Keystone Family Medicine Associates P.C., 28 East 5th Street, Mount Carmel, Pennsylvania, and at 235 West Spruce Street, Shamokin, Pennsylvania. The defendant was licensed by the Commonwealth of Pennsylvania to practice medicine and registered by the Drug Enforcement Administration (DEA) to prescribe Schedule II,

III, IV and V controlled substances. As an osteopathic doctor, Kraynak was authorized to prescribe and/or dispense Schedule II controlled substances to patients and to prescribe medicine to patients, including controlled substances, for legitimate medical purposes and in the usual course of professional practice. The indictment alleges that many of the prescriptions issued by Kraynak were not issued for a legitimate medical purpose and were not issued within the usual course of a professional medical practice.

The 19-count indictment returned December 20, 2017 charges Kraynak with violations of 21 U.S.C. § 841(a) (1) for the distribution and dispensing of controlled substances outside the usual course of professional practice and not for a legitimate medical purpose. (Doc. 3) Counts 1 through 12 concern twelve individual patients. Counts 13 through 17 address five of those twelve patients, and it is alleged in those counts that the defendant's distribution and dispensing of a controlled substance resulted in the deaths of those five patients. Counts 18 and 19 charge violations of 21 U.S.C. § 856(a)(1), for the defendant's maintaining locations at 28 East 5th Street, Mount Carmel, Pennsylvania, and at 235 West Spruce Street, Shamokin, Pennsylvania

for the purpose of unlawfully distributing controlled substances outside the usual course of professional practice and not for a legitimate medical purpose.

A review of the defendant's medical records for the time frame of this indictment, obtained by search warrants during the course of this extensive DEA investigation, show that the records were routinely incomplete or missing and that the medical records failed to contain the required information regarding symptoms observed and reported, diagnosis of condition, direction for use, changes in symptoms observed and reported in their diagnosis of the condition for which the controlled substance was being given and in the directions given to the patient.

B. Administrative Licensing and Medical Board Actions

On April 11, 2012, the Commonwealth of Pennsylvania, Bureau of Professional and Occupational Affairs (BPOA) entered into a Consent Agreement and Order with Kraynak to resolve a show cause order regarding the following allegations:

- During the period of January 2007 through June 2008, Kraynak prescribed large quantities of various controlled substances to seven separate patients.
- Kraynak failed to perform a physical examination of several of the patients pursuant to the prescription of controlled substances to

these patients.

- Kraynak failed to document justification in the medical record for many of the controlled substances that he prescribed for the patients.
- Patients consistently requested new prescriptions for controlled substances prior to the end of their current prescriptions.
- Kraynak prescribed increasing doses of controlled substances to the patients.
- Kraynak did not document pill counts for patients.
- Kraynak did not document a narcotic agreement with patients.
- Kraynak did not document whether urine drug screening was provided to patients.

While admitting no wrongdoing, Kraynak consented to the order issued and agreed with the following:

- Kraynak departed from, or failed to conform to, standards of acceptable and prevailing osteopathic medical practice in regard to the prescribing of controlled substances by a family physician to patients.
- Kraynak agreed to attend and complete the “Intensive Course in Controlled Substance Management” at Case Western Reserve University School of Medicine, which consists of thirty-one hours.
- Kraynak shall institute, within ninety days of the adoption of the Consent Agreement, contracts for the management of patients with complaints of chronic pain and enforce the terms which shall include that all controlled substances be filled at one pharmacy, that all controlled substances be prescribed by Kraynak, and that unannounced urine or serum toxicology screens may be requested.
- Kraynak agrees to engage a professional office management company to review the documentation practices instituted by him

for chronic pain patients.

- Kraynak was also ordered to pay a Civil Penalty of \$2500.00.

GEX 1, 8-9.

On October 28, 2013, the BPOA filed another order to show cause alleging that Kraynak violated the Osteopathic Medical Practice Act by departing from, or failing to conform to standards of acceptable and prevailing osteopathic medical practice in regard to the prescribing of controlled substances by a family physician for three patients. The order to show cause also alleged that Kraynak violated the Osteopath Board regulations by failing to annotate pertinent clinical information in medical records for the patients. GEX 1, 9.

In July 2014, the Pennsylvania State Board of Osteopathic Medicine conducted a hearing on the order to show cause regarding the OTSC. On January 19, 2016, the hearing examiner, in a proposed order, found that Kraynak was not subject to disciplinary action for departing from, or failing to conform to standards of acceptable and prevailing osteopathic medical practice in regard to the prescribing of controlled substances by a family physician, but did find that Kraynak was subject to disciplinary action for violating Board regulations by failing to annotate pertinent clinical information in medical records.

Kraynak was ordered to complete six hours of remedial continuing medical education related to patient medical record documentation, in addition to any standard continuing medical educational requirements imposed by Board regulations. GEX 1, 10-11.

C. PMP and Pharmacy Records

1. PMP Records

During the investigation of Kraynak's prescription practices, DEA investigators reviewed prescription monitoring reports (PMP) based on data collected by the Pennsylvania Prescription Drug Monitoring Program (PDMP), which contain prescription data for all Schedule II controlled substances dispensed by pharmacies in the Commonwealth of Pennsylvania. GEX 1, 21. All states and the District of Columbia currently utilize some form of electronic prescription drug monitoring database in which data from all prescriptions for controlled substances filled by pharmacies within the state are recorded. Data from these state databases is routinely admitted as evidence in federal court when an individual is charged with prescribing or dispensing controlled substances outside the usual course of professional practice.¹

¹ A survey of cases across the nation in which PDMP data was

Pharmacies are required by law in Pennsylvania to report the patient's name, the particular Schedule II controlled substance and dosage dispensed, quantity dispensed, number of days supplied, prescribing physician's name, DEA registration number, and the dispensing pharmacy's name and DEA registration number, as well as the date the prescription was written, the date it was dispensed, and information about the recipient. *See* Pennsylvania P.L. 2911, Act 191.

PMP reports reviewed by DEA investigators showed that – despite two prior show cause orders issued by the BPOA, a consent agreement, two remedial medical education courses on controlled substance management and patient medical record documentation, and review of

admitted, typically without objection, yielded the following non-exhaustive list: *United States v. Mirilishvili*, 2016 U.S. Dist. LEXIS 21268, *14–17 (SDNY 2016) (admitting New York PDMP records); *United States v. Lowe*, 14-cr-00555-LGS (SDNY) (admitting New York PDMP records); *United States v. Wiseberg*, 13-cr-00794-AT (SDNY) (admitting New Jersey PDMP records); *United States v. Boccone*, 11-cr-00592 (EDVA) (admitting Virginia PDMP records); *United States v. Kabov*, 15-cr-00511-DMG (CDCA) (admitting California PDMP records); *United States v. Garg*, 15-cr-0007-JAK (CDCA) (admitting California PDMP records); *United States v. Sun*, 14-cr-00157 (CDCA) (admitting California PDMP records); *United States v. Bamdad*, 08-cr-00506-GW (CDCA) (admitting California PDMP records); *United States v. Mikaelian*, 11-cr-00922-DDP (CDCA) (admitting California PDMP records); *United States v. Gabriel-Diaz*, 12-cr-00011-CJC (CDCA) (admitting California PDMP records).

his patient files by an outside consultant – Kraynak continued to prescribe excessive amounts of Schedule II controlled substances.

Review of PMP reports by DEA investigators disclosed that from May of 2012 until the end of January 2016, Kraynak prescribed 3,622,598 Oxycodone pills. That total number represented 80.62% of all the controlled substances prescribed by him during that period.

Furthermore, from January 1, 2016 through July 31, 2017, Kraynak prescribed an aggregate of 2,792,490 dosage units of oxycodone, hydrocodone, OxyContin and fentanyl to approximately 2,838 patients. This prescription volume made Kraynak the top prescriber for all of the Commonwealth of Pennsylvania for these controlled substances during that 19-month period.

2. Pharmacy Records

In addition to the PMP reports reviewed and analyzed by DEA, the United States intends to introduce records and summaries of records for the local pharmacies that filled his patients' prescriptions, including prescription records for Kraynak's patients maintained by Walmart, RiteAid, CVS, Medicine Shoppe, Belski Community Pharmacy, and Burch's Pharmacy, among others. These pharmacies

reported to DEA investigators similar high-volume prescription totals for Schedule II controlled substances and advised that they often refused to fill prescriptions for his patients because of abnormal volume and frequency of prescriptions and requests for early prescription refills. GEX 1, 19-20.

In reviewing PMP records of Kraynak's prescription activity, DEA investigators identified pharmacies where significant amounts of prescriptions for Schedule II controlled substances were filled for his patients, including Rite Aid, CVS and the Belski Pharmacy, among others, during the period from January 1, 2014 through November 11, 2015. GEX 1, 20. The investigators compared the total dosage units (DU's) dispensed by the pharmacies to the amount prescribed by Kraynak and determined that he was the pharmacies' highest prescriber of Schedule II controlled substances, and, furthermore, that the volume of his prescriptions significantly exceeded the second highest prescribers:

Pharmacy	Total DUs Dispensed by Pharmacy	Amount of DUs Prescribed by Dr. Kraynak	% of DUs Prescribed by Dr. Kraynak	Amount of DUs Prescribed by 2 nd Highest Doctor	% of DUs Prescribed by 2 nd Highest Doctor
Belski	1,073,000	580,000	54%	124,000	11.5%

Rite Aid #2478	1,135,000	485,000	42.7%	40,000	3.5%
Rite Aid #205	624,000	234,000	37.5%	33,000	5.3%
CVS	773,000	196,000	25%	65,000	8.4%

GEX 1, 20-21.

DEA investigators also learned from pharmacy staff that Kraynak's patients frequently tried to obtain early refills of Schedule II controlled substances, that prescriptions were issued days apart by Kraynak, and that pharmacies regularly refused to fill prescriptions written for Kraynak's patients. GEX 1, 20.

D. Referrals from Medical Insurers

Independent of PMP and pharmacy records showing his demonstrated pattern of prescribing unusually large volumes of Schedule II controlled substances, medical insurers, specifically Anthem Blue Cross Blue Shield ("Anthem") and the Medicare and Medicaid programs, in reviewing prescription claims, identified excessive quantities and combinations of controlled substances prescribed by Kraynak and referred their findings to the BPOA and the DEA

Resident Office in Scranton.

1. Anthem Referral to the Board of Osteopathic Medicine

On April 5, 2015, Anthem Blue Cross Blue Shield (“Anthem”) referred Kraynak to the Pennsylvania Board of Osteopathic Medicine based on concerns of inappropriate prescribing of controlled substances and prescribing dangerous combinations of medications. GEX 3.

Anthem included with its referral letter a copy of an investigative report prepared by its pharmacy benefits manager, Express Scripts, concerning prescription drug claims for Kraynak’s patients. GEX 3, 3.

The Express Scripts report summarized findings for a claims review period between January 2012 and November 2014. GEX 3, 1. During that almost three-year period, Express Scripts determined that Kraynak prescribed 54,820 medications, 39% of which were controlled substances, and of the top ten medications prescribed by him, 80% were for narcotics. GEX 3, 1; 4. Express Scripts reported that Kraynak’s prescribing habits differed considerably from other family practitioners in Pennsylvania -- his top ten prescriptions included five types of oxycodone and hydrocodone that are among the Schedule II controlled substances charged in the Indictment, but those substances were not

even listed in the top 10 medications prescribed by other Pennsylvania family medicine physicians like Kraynak. GEX 3, 1; 7.

2. Health Integrity LLC Referral

On June 3, 2015, the DEA Scranton RO received a referral regarding Kraynak from Health Integrity LLC, a Medicare Drug Integrity Contractor for the Centers for Medicare & Medicaid Services. Health Integrity was contracted to perform program safeguard functions to detect, deter and prevent fraud, waste and abuse related to the Medicare Part D Program, which provides funding to insurance plans to pay for the covered prescription drugs of Medicare beneficiaries. Health Integrity reviewed pharmacy claims for the period between January 1, 2013 to December 31, 2013 and identified Kraynak in the “Pill Mill Doctors Proactive Analysis Model” used to analyze claims for irregularities. According to the Health Integrity review of claims for medications prescribed by him, Kraynak had a predicted risk score of 977 on a scale of 1-1000. Based on its review, Health Integrity suspected Kraynak of overprescribing controlled medication and not prescribing in a legitimate course of practice.

E. Combinations of Controlled Substances Prescribed by Kraynak

In addition to the dramatically higher amounts of oxycodone and hydrocodone prescribed by Kraynak as compared to other family physicians in Pennsylvania, the Anthem referral and Express Scripts report identified dangerous combinations of controlled substances prescribed by Kraynak. Although oxycodone and hydrocodone comprised most of the Kraynak patient claims summarized by Express Scripts, the report also identified a less frequently prescribed, but potentially dangerous combination of medications that include benzodiazepine (alprazolam), a muscle relaxer, carisoprodol, and an opioid-based pain medication, oxycodone or hydrocodone. GEX 3, 1; 7-8. According to the Express Scripts report, these combinations of medications have been identified as enhancing the effects of the drugs and creating a “high” that increases the potential for abuse by patients. GEX 3, 7-8.

Dr. Stephen Thomas’s review of patient files and police, toxicology, and autopsy reports for RC, AK, ML, TM, CS, JL, and RW disclosed that, both during and after the claims period reviewed by Express Scripts, Kraynak prescribed those patients combinations of oxycodone, hydrocodone, and benzodiazepine (Alprazolam/Xanax,

Diazepam/Valium), and carisoprodol (Soma). According to Counts 13 through 17 of the Indictment, charging distribution and dispensing of controlled substances resulting in death, Kraynak prescribed patients RC, DH, AK, MI, and CS combinations of multiple controlled substances, including Alprazolam, Hydrocodone, Carisprodol, Temazepam, Oxycodone, Diazepam, and Zolpidem. Doc. 3, 18-19. Based on patient medical records, pharmacy and prescription data, witness testimony, laboratory, toxicology, police and autopsy reports, and other information set forth in his report, Dr. Thomas opined that these combinations of controlled substances prescribed by Kraynak resulted in the death of the patients and were outside the usual course of professional practice and not for legitimate medical purpose.

II. ARGUMENT

The defendant seeks to preclude the jury from hearing relevant PMP data concerning the substantial amount of prescriptions issued by Kraynak for Schedule II controlled substances during the period charged in the indictment. He also asks the Court to preclude any evidence about the various combinations of controlled substances prescribed by him and a report sent by an insurer, Anthem Blue Cross

Blue Shield (“Anthem”) to the Pennsylvania Board of Osteopathic Medicine concerning the high volume of Schedule II controlled substances prescribed to patients insured by Anthem. Doc. 119, 3.

Kraynak contends that the evidence he seeks to exclude is irrelevant and prejudicial under Federal Rules of Evidence 404(b) and 403. *Id.* But, as presented below, the disputed evidence directly demonstrates Kraynak’s knowing and intentional distribution of Schedule II controlled substances outside the usual course of professional practice and without legitimate medical purpose, not just to specific patients but across his entire medical practice. Alternatively, the evidence is admissible under Federal of Evidence 404(b) to prove a common, plan, design and scheme to prescribe controlled substances for other than legitimate medical purposes and not in the usual course of professional practice, Kraynak’s knowledge and understanding of legitimate medical purposes and the usual course of professional practice, his intent to prescribe excessive amounts of controlled substances despite knowledge of those professional standards and requirements, and the absence of mistake, accident, or other innocent reason in prescribing excessive and inappropriate quantities and

combinations of controlled substances.

A. Elements of the Offenses

Because he was a physician during the relevant time period, for Kraynak to be found guilty of the drug distribution in violation of 21 U.S.C. § 841(a)(1) as charged in Counts 1 through 12, the United States must prove several basic elements:

First, that the defendant distributed and dispensed, or caused to be distributed or dispensed, a mixture or substance containing a controlled substance;

Second, that the defendant distributed and dispensed, or caused to be distributed or dispensed, the controlled substance outside the usual course of professional practice and not for a legitimate medical purpose;

Third, that the defendant distributed and dispensed, or caused to be distributed or dispensed, the controlled substance while knowing or intending that the distribution was outside the usual course of professional practice and not for a legitimate medical purpose; and

Fourth, that the controlled substance was the substance identified in the indictment.

See United States v. Polan, 970 F.3d 1280, 1282 (3d Cir. 1992); Third

Circuit Model Criminal Jury Instructions, No. 6.21 841B (2015)

(adapted to the charges in this case); *see also United States v. Zielke*,

2021 WL 1163868 *5 (W.D. Pa. March 26, 2021) (slip opinion). Counts

13 through 17 require proof of the same elements and the additional element that death resulted from the use of the controlled substances. *United States v. Burrage*, 134 S.Ct. 881 (2014). Counts 18 and 19 likewise require proof that Kraynak opened and maintained a place for purposes of distributing controlled substances outside the usual course of professional practice and without legitimate medical purpose. *See* 21 U.S.C. § 856(a)(1).

The act of prescribing a controlled substance constitutes distribution. *See* 21 U.S.C. §§ 802(8) (11). In *United States v. Moore*, 423 U.S. 122 (1975), the Supreme Court specifically held that “registered physicians can be prosecuted under § 841(a)(1) when their activities fall outside the usual course of professional practice.” A medical professional’s prescription of a controlled substance is lawful only if “issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.”² 21

² While noting some uncertainty about the relationship between the language “for a legitimate medical purpose” and “outside the usual course of professional practice,” the Third Circuit has never opined on that issue. *See United States v. Shaker*, 827 Fed.Appx. 204, 207 n. 4 (3d Cir. 2020). Nevertheless, the Third Circuit has acknowledged that a number of courts of appeals have held that there is no difference in the meanings of the statutory phrase “in the course of professional

C.F.R § 1306.04. In addition, the United States must show that Kraynak prescribed Schedule II controlled substance with the knowledge and intent that his conduct fell outside the usual course of professional practice. *See* Third Circuit Model Criminal Jury Instruction, No. 6.21.841-4 (2015).

The central elements of all the counts in the Indictment, therefore, is whether Kraynak prescribed controlled substances outside the usual course of professional practice, without a legitimate medical purpose, and that he did so knowingly and intentionally. Based on the limited summary of his medical expert's opinion, it is expected that Kraynak will dispute those elements and contend that his prescribing practices were within the usual course of professional practice. Moreover, the United States anticipates that he will dispute all elements of the drug charges at trial, by claiming that his conduct was consistent with the

practice” and the regulatory phrase “legitimate medical purpose.” *Id. United States v. Rottschaefer*, 178 Fed.Appx. 145, 147-48 (3d Cir. 2006). In particular, the Third Circuit noted that *United States v. Nelson*, 363 F.3d 1227, 1231-32 (10th Cir. 2004) supports the proposition that the jury need only find either that a prescription was made outside the usual course of professional practice or that it was not for a legitimate medical purpose in order to convict a physician under §841. *Shaker* at *207 n. 4; *see also Rottsschaeffer* at 1447-48 (quoting *Nelson*).

medical profession's standard of care, and that he intended to engage in legitimate medical treatment. One of the ways the United States intends to prove these elements is with evidence showing the staggering volume, frequency, and combinations of medications prescribed by Kraynak across his entire practice, over the extended period of criminal conduct charged in the Indictment.

B. Practice-wide prescription data directly proves elements of the offenses.

There is no question that the PMP and Anthem prescription data concerning the type, frequency, and combination of drugs prescribed by Kraynak are highly relevant to prove essential elements of the offense, namely Kraynak's knowledge, intent, and purpose in prescribing controlled substances and whether his conduct was outside the usual course of professional practice. The Eleventh Circuit's opinion in *United States v. Merrill* offers valuable insight on this point:

[E]vidence of the quantity and combination of prescriptions Merrill wrote during the relevant period is directly related to the issue of whether Merrill committed healthcare fraud by "prescribing excessive and inappropriate quantities and combinations of controlled substances to patients outside the usual course of professional practice" and whether Merrill was relieved of liability under the Controlled Substance Act because he acted in the "usual course of professional practice." A jury may consider

prescription data sets outside those specifically charged in the indictment to determine whether a physician has exceeded “the legitimate bounds of medical practice” and “as evidence of plan, design, or scheme.”

513 F.3d at 1302 (citing *United States v. Harrison*, 651 F.2d 353, 355 (5th Cir. July 20, 1981) (concluding that in considering whether the defendant exceeded legitimate medical practice, “prescriptions issued at other times were admissible as evidence of plan, design, or scheme.”)).

The information that Kraynak seeks to exclude – PMP reporting concerning his practice-wide prescriptions of Schedule II controlled substances, Anthem’s report concerning a high-volume of pharmacy claims for those controlled substances, and the dangerous combinations of oxycodone, benzodiazepine and carisoprodol reflected in those records – represents direct evidence relevant as to all the counts in the Indictment. This intrinsic evidence of Kraynak’s practice-wide and individual patterns of prescription activity proves elements shared by all the offenses charged, namely that the excessive and inappropriate amounts and combinations of Schedule II controlled substances prescribed by Kraynak did not comply with usual professional practice and lacked legitimate medical purpose, and that he nevertheless knowingly and intentionally prescribed them.

The extent to which Kraynak's extensive and repeated patterns of prescription activity departed from the usual professional practice is direct evidence of this element of proof. *See Merrill*, 513 F.3d at 1302-1303 (individual prescriptions and summary of practice-wide prescription activity, including those not charged in indictment, was direct evidence proving element of dispensing drugs "outside the usual course of professional practice"). Likewise, the combinations of the medications that Kraynak prescribed constitute direct evidence concerning whether the defendant prescribed those substances consistent with usual professional practice and whether the prescriptions had a legitimate medical purpose. *Id.* at 1302 (evidence of quantity and combination of prescriptions written during the relevant period is directly related to whether doctor prescribed excessive and inappropriate quantities of controlled substances to parties outside usual course of medical practice).

Counts 13 through 17 charge Kraynak with prescribing combinations of multiple drugs resulting in the deaths of five patients. Evidence in PMP reports and prescription claims summaries showing practice-wide prescriptions for dangerous combinations of drugs are

direct evidence that the prescriptions were outside the scope of usual professional practice. And, even if not intrinsic evidence, under Rule 404(b) the evidence is nevertheless admissible. As the Ninth Circuit held in *United States v. Lague*, “uncharged prescriptions of controlled substances in enormous quantities, and in dangerous combinations, support a reasonable inference that the underlying prescriptions were issued outside the usual course of professional practice and without a legitimate medical purpose.” 971 F.3d 1032, 1040 (9th Cir. 2020), *cert. denied*, 141 S. Ct. 1695 (2021).

Moreover, Counts 18 and 19 allege that Kraynak maintained drug-involved premises at two medical offices over an extended period, from January 2006 and continuing through November 2017, for the purpose of distributing Schedule II controlled substances outside the usual course of professional practice and without legitimate medical purpose. The PMP records and insurance claims records, such as those reported by Anthem and the Medicare and Medicaid programs fall squarely within the period identified in Counts 18 and 19 and are therefore relevant to prove that he maintained drug-involved premises at those medical offices, during that time fram. As Judge Caputo held

in *United States v. Fuhai Li*, a physician's practice-wide prescription data, including PMP data and prescription records, substantively supported the jury's finding of guilt on a drug involved-premises count in violation of 21 U.S.C. 856(a)(1). 2019 WL 1126093 at *8-*9 (M.D.Pa. March 12, 2019).

In sum, the PMP and Anthem records, and other summaries and compilations of pharmacy records prepared by DEA analysts concerning Kraynak's practice-wide prescription activity are admissible both as direct evidence to prove that he knowingly and intentionally dispensed controlled substances without a legitimate medical purpose and outside the usual course of professional practice, and further to show that he maintained drug-involved premises at his two medical offices. Moreover, the combinations of controlled substances reflected in the PMP reports, prescription claims review, and pharmacy records are directly relevant to whether the prescriptions of combinations of multiple medications resulting in the patients' deaths charged in Counts 13 through 17 were outside the usual course of professional conduct and not for legitimate medical purpose.

Finally, although he does not raise it in his motion, evidence

concerning the overdose deaths for the deceased patients, both charged and not charged in the indictment, is directly relevant to prove both that the prescriptions were outside of the usual course of professional practice and had no legitimate medical purpose. Twelve of Kraynak's patients died during the period charged in the Indictment and the evidence will show that despite their deaths he continued to unlawfully dispense controlled substances to other patients outside the usual course of professional practice. *See United States v. Zielke*, 2021 WL 1163868 at *5-*6 (evidence of patient deaths during time period relevant to defendant's knowledge that patients were misusing prescriptions and that his continuing distribution of narcotics was outside the scope of usual professional practice and not for legitimate medical purposes); *United States v. Bourlier*, 518 Fed.Appx. 848, 855 (11th Cir. 2013) (affirming admission of patient overdose deaths not charged in indictment where deceased patients were receiving controlled substance prescriptions during same time period alleged in the counts of the indictment; evidence could be considered by jury in determining whether defendant distributed controlled substances without a legitimate medical purpose and outside the usual course of

professional practice and had knowledge patients were misusing prescriptions).

C. The disputed evidence is admissible under Rule 404(b).

Even assuming that the PMP reports and the Anthem claims summary are not intrinsic evidence, they nevertheless are admissible under Rule 404(b). The massive scale of Kraynak's prescription activity as reflected in the PMP and Anthem records, on both the practice-wide and the individual patient levels, is admissible evidence of Kraynak's plan, design, pattern and scheme to dispense drugs outside the usual course of professional practice under Federal Rule of Evidence 404(b). As the Eleventh Circuit stated in *Merrill*, "To the extent that it can be argued that *each* prescription is uncharged conduct, each is admissible under Rule 404(b) to show evidence of a plan. [emphasis in original]" 523 F.3d at 1303 (citing *United States v. Harrison*, 651 F.2d 353, 355 (5th Cir. 1981)).

The evidence of Kraynak's extensive prescription of Schedule II controlled substances also proves his knowledge and understanding of legitimate medical purposes and the usual course of professional practice, his intent to prescribe excessive amounts of controlled

substances despite knowledge of those professional standards, and the absence of mistake, accident, or other innocent reason in prescribing excessive and inappropriate quantities and combinations of controlled substances. Uncharged practice-wide prescription data from PMP reports, prescription benefits claims, and pharmacies are highly probative of Kraynak's unlawful intent to distribute outside usual professional practice and undercut any claim that the charged prescriptions amounted to "a few bad judgments." *Lague*, 971 F.3d at 1040.

The sheer volume, duration and frequency of Kraynak's prescriptions for controlled substances during the extended period between 2012 and 2016, when he is alleged to have illegally distributed controlled substances, and the 11-year period between 2006 to 2017, when he is alleged to have maintained drug-involved premises, establish plainly that his prescription practices were not the result of accident or mistake and they lay squarely within the charged course of conduct and relevant time span. The PMP records report prescription activity from April 2013 to October 2017, Anthem's Express Scripts report summaries prescription claims between January 2012 and

November 2014, and the Medicare Medicaid claims summary covers a range from January 2013 through December 2013 – periods of conduct well within the 2012 to 2016 range of the 17 drug distribution counts and the 2006 to 2017 range for the two maintaining drug-involved premises counts.

But apart from the massive amount of Schedule II drugs reflected in the PMP reports and the Anthem and Medicare and Medicaid prescription claims review, the timing of the abnormal prescription activity identified in that data is highly relevant to whether Kraynak knew and understood that his practice-wide and individual patient prescription activities were not for legitimate medical purposes and breached the usual professional practice. Notably, prior to Anthem's referral on May 5, 2015, Kraynak had entered into a consent agreement and order in January 2012 with the Commonwealth of Pennsylvania, Bureau of Professional and Occupational Affairs concerning allegations, among others, that he prescribed large quantities of various controlled substances to patients. Under the consent agreement, Kraynak completed a 31-hour intensive course in controlled substance management at Case Western Reserve University School of Medicine in

May 2012 and agreed to have an outside medical records management consultant review his patient files and recordkeeping procedures.

Moreover, on October 22, 2013, the Commonwealth filed a second show cause order alleging that Kraynak prescribed excessive amounts of Schedule II controlled substances to three patients and did not adequately document the patients' medical files. The second show cause hearing was finally resolved in January 2016 and Kraynak was required to take six additional hours of remedial continuing medical education related to patient medical record documentation.³

Despite two prior show cause orders, and two separate courses of remedial study, the Express Script claims report showed that Kraynak continued to inappropriately prescribe controlled substances in excessive amounts and/or without medical necessity during the pharmacy claims period between January 2012 and November 2014. Express Scripts identified irregular prescription activity over that 36-month period which followed the initial consent agreement in January

³ At the hearing on the second show cause order, held July 31, 2014, Kraynak testified that the course he attended at Case Western Reserve was "excellent" and he "learned a lot from it" about documenting patient files, the "proper prescribing of medications", urine testing, and how to identify patients who are addicted to controlled substances.

2012 and overlapped the 31-hour intensive course completed in May 2012 and the extended pendency of the second show cause hearing resolved in 2016. Likewise, during their review of PMP and pharmacy records, DEA investigators noted the same pattern and volume of prescription activity following the show cause orders and his participation in remedial medical education courses. The disputed evidence thus shows that Kraynak continued to dispense large volumes of Schedule II controlled substances even after being professionally disciplined and taking remedial classes.

And, perhaps most important, under Rule 404(b), the uncharged PMP prescription data and claims analysis of pharmacy benefits providers like Anthem and the Medicare Medicaid programs, which showed prescriptions in vast quantities and in dangerous combinations, support a reasonable inference that the underlying prescriptions were issued outside the usual course of professional practice and without legitimate purpose. *Lague*, 971 F.3d at 1040. In determining whether Kraynak exceeded the legitimate bounds of medical practice, the jury, therefore, should be permitted to consider prescription activity outside those specifically charged in the indictment. *Merrill*, 513 F.3d at 1303.

Finally, the probative value of the PMP data, the Anthem prescription benefits report, and the combinations of controlled substances prescribed outweighs any risk of unfair prejudice, confusion of issues, misleading the jury, or needlessly presenting cumulative evidence. Those records will be presented through summaries and charts, rather than through the voluminous data of Kraynak's many thousands of prescriptions for Schedule II controlled substances. The evidence will be presented with a focus on the medical purpose of the prescriptions, whether they were within usual professional practice, and Kraynak's plan, design and intent in dispensing the drugs. Any potential risk of prejudice will be minimized through the Court's instructions on the elements related to the defendant's knowledge and intent, medical purpose, and usual professional practice and by any additional limiting instructions on the jury's consideration of the evidence. *See, e.g., United States v. Zielke*, 2021 WL 1163868*6-*7; *United States v. Werther*, 2013 WL 5309451 at *9 (E.D.Pa. Sept. 23, 2013).

I. CONCLUSION

For the reasons stated herein, the Government respectfully requests that the defendant's motion *in limine* be denied.

Respectfully submitted,

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Dated: June 21, 2021

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA)	NO. 4:17-CR-00403
)	
v.)	
)	(JUDGE BRANN)
)	
RAYMOND KRAYNAK,)	
Defendant)	(ELECTRONICALLY FILED)

CERTIFICATE OF SERVICE

The undersigned hereby certifies that she is an employee in the Office of the United States Attorney for the Middle District of Pennsylvania and is a person of such age and discretion to be competent to serve papers.

That this 21st day of June 2021, she served a copy of the attached

GOVERNMENT'S BRIEF IN OPPOSITION TO DEFENDANT'S
MOTION *IN LIMINE* TO PRECLUDE EVIDENCE
UNDER F.R.E. 402, 403 AND 404

Electronically to:

Thomas Thorton, Esquire
Federal Public Defender
Thomas_Thorton@fd.org

Gerald Lord, Esquire
Federal Public Defender
Gerald_Lord@fd.org

/s/ Tammy S. Folmar
Tamy S. Folmar
Legal Assistant